



ORIGINAL ARTICLE

KISSING STENT TECHNIQUE FOR AORTO-ILIAC OCCLUSIVE DISEASE: 5-YEAR FOLLOW UP

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Abstract

Occlusive disease of the aorta and iliac arteries may lead to incapacitating claudication or, critical limb ischemia. Until recently, symptomatic stenoses or occlusions at the aortoiliac bifurcation were generally treated surgically with aorto-bi-femoral grafts. However, although these interventions are highly effective (5-year patency rate of more than 91%), they are also associated with significant morbidity (8.3%) and mortality (3.3%). As an alternative to surgical treatment, endovascular intervention deploying percutaneous transluminal angioplasty with placement of aortoiliac kissing stents has been introduced to treat aorto-iliac occlusive disease. The aim of this study is to show the results of 5-year follow up of cases treated with the Kissing stent technique, done between June 2006 and May 2008, as regards primary and secondary patency rates, clinical improvement, ABI, complications (and how managed) and mortality. The study included sixty-two patients; twelve of them with TASC A(19.3%), thirty three with TASC B (53.3%), and seventeen selected cases of TASC C (27.4%)(those not extending to or involving the common femoral artery). Five-year primary and secondary patency rates were 71% and 81%, respectively. Hemodynamically significant restenosis developed in nine patients (14.5%). The management of restenosis was endovascular in eight patients and was successful in all (balloon dilation-PTA alone- in four, dilataion and restenting in the other four) and operative in one patient who developed aortic occlusion and underwent aortobifemoral grafting. Seven cases (11.3%) were totally occluded; 3 redilated and 4 operated upon. Most common intra-procedural complications were, access site hematomas distal embolization, and arterial dissections. The majority of complications could be treated using percutaneous or noninvasive techniques, only one case of thrombosis required urgent Aorto-bi-femoral bypass. One patient had major amputation due to distal disease and with patent stents. Conclusion: Endovascular treatment of extensive AIOD can be performed successfully in TASC A, B and selected patients of TASC C. Although primary patency rates are lower than those reported for surgical revascularization, reinterventions can often be performed percutaneously, with secondary patency fairly comparable to surgical repair. TASC D and TASC C with involvement of CFA should be primarily treated surgically.

Keywords: Endovascular, arterial occlusive disease, abdominal aorta, iliac artery, Le riche syndrome, angioplasty, kissing stent.

INTRODUCTION

Traditional treatment of aortoiliac stenoses or occlusions was surgery; the procedure of choice is aortobifemoral bypass.⁽¹⁾ Despite the excellent patency rates, surgery has several disadvantages, including the need for general anesthesia, longer hospitalization and recovery from the required incision, loss of sexual function, and high cost.⁽²⁾ Kissing balloon angioplasty was proposed as an alternative to surgery; although the technique was found to be effective and durable, there was a significant incidence of dissection, thrombosis, and residual stenosis.^(3,4) The kissing stents technique, which involves simultaneous implantation of two stents at the aortic bifurcation, was presumed to overcome these drawbacks. Today, with the refinements in stent technology, the kissing stents technique has largely replaced kissing balloon dilation for the treatment of aortoiliac occlusive disease.⁽⁵⁾

Lesion-specific indications for the endovascular therapy of aortoiliac occlusive disease can be guided by the Trans-Atlantic Inter-Society Consensus (TASC) guidelines.⁽⁶⁾ The TASC classification system was recently revised to offer more current guidelines on the use of endovascular therapy based on lesion anatomy.⁽⁷⁾ In general, endovascular therapy is the recommended first-line therapy for TASC A and B lesions and increasingly for TASC C lesions as endovascular techniques improve. Good-risk patients with TASC type C disease can also be treated with open surgery, depending on patient preference. Surgery is usually recommended for TASC D lesions. High-risk patients with TASC C and D disease, critical limb ischemia, and advanced co-morbidities such as severe chronic obstructive pulmonary disease, unreconstructable coronary artery disease, or a low cardiac ejection fraction may be treated with endovascular therapy, acknowledging that this approach will be less durable than open surgical options.⁽⁸⁾

Table 1. Showing the TASC classification.

TASC lesion	Lesion description
A	<ul style="list-style-type: none"> • Unilateral or bilateral stenosis of CIA • Unilateral or bilateral single short (<3 cm) stenosis of EIA
B	<ul style="list-style-type: none"> • Short (<3 cm) stenosis of infrarenal aorta • Unilateral CIA occlusion • Single or multiple stenosis totaling 3-10 cm involving the EIA but not extending into the CFA • Unilateral EIA occlusion not involving the origins of the internal iliac or CFA
C	<ul style="list-style-type: none"> • Bilateral CIA occlusions • Bilateral EIA stenosis 3-10 cm long but not extending into the CFA • Unilateral EIA stenosis extending into the CFA • Unilateral EIA occlusion involving the origin of the internal iliac and/or CFA • Heavily calcified unilateral EIA occlusion with/without involvement of origins or internal iliac and/or CFA
D	<ul style="list-style-type: none"> • Intrarenal aortoiliac occlusion • Diffuse disease involving the aorta and both iliac arteries requiring treatment • Diffuse multiple stenosis involving the unilateral CIA, EIA, and CFA • Unilateral occlusions of both CIA and EIA • Bilateral occlusions of EIA • Iliac stenosis in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery

The Kissing Stent technique has been introduced in our institute since almost 20 years. Earlier it was used to treat TASC A & B cases only, then with the advancement to the technical skills and the endovascular material, also selected cases of TASC C could be successfully treated (excluding cases with involvement of the Common Femoral Artery). Patients with TASC D and extensive TASC C were scheduled for surgical intervention, mostly aorto-bifemoral-bypass or extra-anatomical bypass according to their general state. The aim of this study is to show the results of 5-year follow up of cases treated with the Kissing Stent technique.

PATIENTS AND METHODS

During the period between June 2006 and May 2008, and from all different types of ischemic patients admitted to our vascular unit in Kasr AL-Ainy hospitals, 89 cases had aorto-iliac disease (isolated or combined with a distal lesion). After Radiological examination mostly by CT angiography or DSA, only 62 cases were included in the study. These cases were; TASC A 12 cases, TASC B 33 cases, TASC C 17 cases. The remaining 27 cases were; TASC D 23 cases, and 4 cases has extensive TASC C lesion with involvement of the CFA and/or the mouth of the profunda femoris

artery necessitating operative intervention. Patient characteristics and Clinical presentation were described in table (2) Patients were examined thoroughly, full laboratory tests were done especially kidney functions (patients with creatinine level >2mg% were be excluded). Chest and cardiological examination were done, and all patients included in our study had duplex examination of the arterial system of both lower limbs and the aorto-iliac segment, with ABI and segmental pressure measurements whenever possible. Lesions were classified according to TransAtlantic Inter-Society Consensus (TASC) classification of disease severity. All patients received clopidogrel; 4x75mg at the night of the procedure. For placement of aortoiliac kissing stents, bilateral retrograde femoral artery punctures were performed. Guide wires were placed through a 6F sheath. In case of iliac artery occlusion, the wire loop technique was used, using the contralateral CIA, cross-over technique, the occlusion was passed with 0.035-inch Terumo wire till the SFA. With the guide wire as a marker, the ipsilateral CFA was punctured under fluoroscopy, and a second 6 F catheter was placed. This technique of initial contralateral passage of the occlusion minimizes the risk of subintimal tracking in the area of the aortic bifurcation which subsequently leads to dissection and failure of deployment of the balloon expandable stent. In bilateral occlusions the brachial artery approach was used, If necessary, predilatation was performed with a balloon catheter (undersized balloons 5-7mm), with the kissing technique. Balloons were positioned bilaterally and inflated simultaneously using an inflation device. After that, kissing stents were placed. In all cases, primary implantation of balloon expandable stents (7-8 mm) was performed to stabilize the recanalized vessel segment and positioned at the aortic bifurcation extending 3-5mm into the distal aorta; this allows optimal reconstruction of the bifurcation. In all cases stent implantation was performed simultaneously on both sides with the kissing balloon technique. Stent types used in this study were balloon expandable stents 6-8 mm according to the case, according to availability from different companies; Cordis, Cook and Boston Scientific. Stent lengths varied from 4 to 10 cm according to the lesions. Two interventionalists deployed all stents. During intervention, all patients received 5000 U heparin intra-arterially. The pressure gradient was measured at the end of each procedure. If any residual pressure gradient was present, further balloon dilatation was performed Post dilatation balloon angioplasty was needed in some cases after mounting of the stent in case of residual stenosis in the dilated and stented artery. A balloon of the same caliber and size as the one used for mounting the stent was used.

Post procedural treatment: The femoral sheaths were removed 6-10 hours later. Thereafter patients continued on clopidogrel 75mg/day, and aspirin 150 mg/day, in addition to statins.

Follow-up Protocol: Patients were followed up clinically after 1 week and 1 month after discharge and

thereafter at 3- monthly intervals for the 1st year. An arterial duplex was done every 6 months thereafter, with calculation of ABI. Angiography was only done if symptoms recurred or complications appeared. 'Technical success'' was defined as restored patency of the vessel with an angiographic residual diameter stenosis of less than 30% and a residual translesional pressure gradient of less than 10%. "Hemodynamic success'' was defined as an ABI more than 0.9. "Clinical success'' was defined by an improvement of walking distance (intermittent claudication). Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS Inc, Chicago, IL). Primary Patency was defined as uninterrupted patency with no procedures performed, and Secondary Patency was defined as patency of the target vessel after reintervention. Patency rates were calculated according to the Kaplan-Meier life-table method. Risk factors for restenosis or occlusion of the stents were analyzed with Kaplan-Meier curves and a multivariate analysis by means of a Cox proportional hazard model. A P value of less than .05 was considered to be statistically significant.

Table 2. Showing the patient characteristics.

PATIENT CHARACTERISTICS	
Characteristics (62)	No. of patients
Male: Female	44:18
Median age (range in years)	58 (36-75)
Symptoms at presentation:	
- incapacitating intermittent claudication	47
- rest pain	5
- nonhealing ulcers	15
Cardiovascular risk factors:	
- diabetes mellitus	13
- hypertension	20
- hyperlipoproteinemia	39
- smoking	42
- family history with cardiovascular events	13

RESULTS

Sixty-two patients were included in the study. The patient characteristics are summarized in Table 2. All patients were treated with balloon expandable kissing stents. Lesions were classified as TASC A in 12 patients, TASC B in 33 patients, TASC C (not involving the CFA) in 17 patients. An additional external iliac self-expandable stents was placed in 2 cases which had significant stenosis in the external iliac arteries. Technical success was achieved in 98.39%, one case had intra procedural thrombosis of the CIA, that could not be managed percutaneously and the patient underwent urgent Aorto-bi-femoral bypass. One patient with CIA total occlusion had iliac and aortic dissection during introduction of the wire and was managed intra-procedural by contralateral cross-over approach. Six

patients (9.67%), developed an access site hematoma in the inguinal region, which dissolved spontaneously in all patients. Two patients (3.22%) had distal embolization in the form of blue-toe syndrome, that was treated conservatively by vasodilators and antiplatelets. No cardiopulmonary or renal complications were seen except in one diabetic patient (1.61%) who developed slight renal impairment (his serum creatinine level became 4.2 mg% 48 hours after the procedure) and was managed conservatively and restored his normal kidney functions (serum creatinine became 0.8 mg%) within 3 weeks.

As regards our results for the 62 patients, and apart from the one patient who was converted to immediate aorto-bi-femoral bypass after intra-procedural dissection, "Clinical success" was seen in 59 patients (95.1%). Of these, 55 patients were free of symptoms; with marked improvement of their walking distance, healing of the indolent ulcers and disappearance of the rest pain. In 2 patients, symptoms were not improved, the rest pain was still present, and no improvement in the ulcer healing. These patients had distal disease, one of them did additional PTA of the SFA, with marked improvement of the symptoms, and the other underwent fem-distal bypass (using reversed vein graft), which unfortunately failed and above knee amputation was done in the presence of patent aorto-iliac segment.

ABI increased from a median of 0.72 to 0.92. "Hemodynamic success" was found in 58 patients

(93.5%), with an improvement of the ABI to a value greater than 0.9. In addition, the 3 patients who did not have an improvement in ABI did have clinical success with disappearance of symptoms, (complete healing of the ulcer, and improvement of the walking distance).

After a median follow-up of 72 months (range 60-84 months), a significant restenosis of the stents occurred in 9 patients (14.5%), one patient of them had aortic involvement as well so he underwent aorto-bi-femoral bypass. The remaining 8 patients were treated Endovascularly; four patients by redilatation (PTA alone) and 4 of them needed restenting (in addition to the PTA). Seven patients (11.3%) had total occlusion of the stents, 3 of them were successfully redilated (PTA only), and 4 underwent surgery; two aorto-bi-femoral bypass and 2 axillo-bi-femoral bypass (due to bad cardiac condition of the patients). The median time interval between stent placement and restenosis or occlusion was 17 months (range 1-60 months). Most of the cases with restenosis or occlusion appeared between the 1st and the 2nd year of follow-up.

The primary patency rate at the 1st, 2nd and 5th years were 86%, 75% and 71% respectively. The secondary patency rate was 92% after 1 year and 87% after 2 years. At the last outpatient department's visit (after 5 years), secondary patency rate was 81%.

In this study, there was no (0%) 30-day immediate post-procedural mortality.



Diagram 1. a) occluded left CIA and stenosed right CIA b)kissing balloons c) angiogram with kissing stents.



Diagram 2. a) bilateral CIA stenosis, b)right EIA total occlusion. c)kissing balloons d)angiogram after kissing stents and right EIA self-expandable stent.

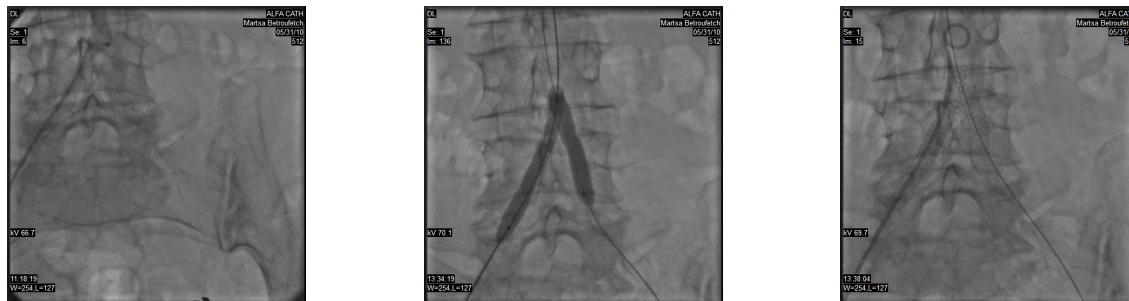


Diagram 3. a)right CIA severe stenosis,left CIA total occlusion.b) kissing balloons c) kissing stents

DISCUSSION

Endovascular treatment of symptomatic occlusive disease at the aortic bifurcation by PTA and kissing stents placement was first described by Palmaz et al.⁽⁹⁾ and Kuffer et al.⁽¹⁰⁾ in 1991. By means of simultaneous bilateral inflation of similar sized balloons, the aortic bifurcation can be optimally dilated without the potential risk of dislodgement of atherosclerotic or thrombotic material in the contralateral iliac artery that is sometimes seen with PTA alone.

Endovascular therapy currently has been firmly established as the treatment of choice for localized Aortoiliac occlusive disease. The role of endovascular techniques in the management of extensive and complex aortoiliac disease, on the other hand, is still controversial.⁽²⁾ For these patients, the TASC multidisciplinary guidelines recommend operative reconstruction, unless operative risk is prohibitive.^(6,7) Long-term patency rates of aortobifemoral bypass graft are excellent (85%-92%), with modest operative mortality.^(11,12) However, perioperative morbidity of surgical revascularization is substantial, while the time-period before return to normal activities and the effects on sexual function are also important to consider. Systemic or major morbidity rates are reported up to 10%, with overall morbidity 11% to 32%. Endovascular treatment is a less invasive management option, potentially reducing morbidity. Moreover, when the outcome does not meet expectations, patients may still be referred for conventional surgical therapy without much "lost". The development of new technologies and techniques has led to increasing use of endovascular techniques in the treatment of extensive AIOD.^(13,14)

In the current study, stent deployment of kissing stents was successful in almost all cases, leading to a 98.39% technical success rate, almost similar to other studies.^(5,14-17) In the present series, restenosis or total occlusion of the stent was seen in 25% of patients (16 patients) and primary patency rate had decreased to 86% after 1 year and 75% after 2 years. This is comparable to reported patency rates in the study of Greiner et al.⁽³⁾ and Mohamed et al.,⁽⁴⁾ who found a primary patency rate of 91% and 81% at 1 year and 65%

and 58% after 2 years respectively. These differences in the primary and secondary patency rates in the result of the current study and the results mentioned by other studies maybe attributed to a fewer number of patients in our study than the others, and also due to the higher number of patients with TASC A and B patients included in the other studies compared to our study. In our study the patients mostly present to seek medical advice with late TASC B or C lesions, not to mention mostly TASC D that necessitates surgical intervention. Brittenden et al.,⁽¹⁸⁾ Scheinert et al.⁽¹⁹⁾ and Haulon et al.⁽²⁰⁾ reported better results with a primary patency rate of 92% after 20 months, 87% at 2 years, and 80% after 3 years, respectively. Nevertheless, these rates are still inferior to primary patency rates of open surgery with aortic bifurcation grafts with a 5-year patency of 91% and a 10-year patency of 87%.⁽¹²⁾

In the current study, most patients with restenosis and total occlusion could be treated endovascularly, and only 5 patients (8.05%) eventually required surgical treatment. This is almost consistent with the results of Greiner et al.,⁽³⁾ who also found that most patients with restenosis could be treated successfully with angioplasty and only 3 of 25 (12%) patients were finally treated surgically with aortobifemoral bypassgrafting.⁽³⁾ Scheinert et al.⁽¹⁹⁾ successfully treated all restenosis with balloon angioplasty and thus achieved a secondary angiographic and clinical patency of 100% in 48 patients.⁽¹⁹⁾ Although reintervention is regularly indicated, the endovascular treatment of aortoiliac occlusive disease with distal aortic or kissing stents – with the aim of limb salvage and not only patency- can prevent surgical intervention (with its associated morbidity and mortality) in the majority of patients.

Apart from a groin hematoma in 9.67% of patients, minor distal embolization in 3.22% and slight renal impairment (elevation of the renal functions not requiring dialysis) in 1.61%, no severe complications were seen in the current study, relatively similar to other studies.^(3,4,15,21,22) Major complications, such as vessel ruptures, distal embolizations and thromboses, are usually immediately solved with covered stents, aspiration and thrombolysis. The frequency of major complications in different studies ranged between 2-

5%⁽²²⁻²⁴⁾ (in our study, we had only 1 case (1.61%), with iliac dissection and thrombosis but was converted to surgery). A study by Fournau,⁽²¹⁾ in a systematic review of cases revealed complications between 3% and 45%.

Kissing stent treatment of AIOD significantly reduces the 30-day mortality compared to surgery, in this study, there was no 30-day post-procedural mortality (0% early mortality). This is well in comparison with previous studies of kissing stents that report early mortality of 0-2.3%.^(3,24-26)

Risk factors influencing restenosis or occlusion of the stent could not be identified in the present study, perhaps because of the limited number of patients, but no trends to significance were seen. Restenosis of the stent can occur as the result of several mechanisms. Often it is caused by intrastent hyperplasia that can occur as the result of thrombus formation, inflammatory reaction, and periarteritis on an injured endothelium. In addition, altered flow patterns may contribute to the accelerated formation of intimal hyperplasia.^(27,28) Ostia of major arterial branches, such as the aortic bifurcation, are prone to severe atherosclerotic changes of the vessel wall with extensive calcification.⁽²⁷⁾ Thus, angioplasty with direct stent placement in this area (without predilation) may have an decreased risk for restenosis, due to less intimal hyperplasia.⁽²⁹⁾ To reduce the incidence of restenosis of the stent, anticoagulant therapy may play a role. For elective coronary stenting, the combination of clopidogrel or ticlopidine with aspirin has been proven to be effective in decreasing the rate of stent thrombosis and myocardial injury.^(22,27) However, for aortic or iliac stents, the same effect has not been established and has to be studied further.

In conclusion Endovascular treatment of aorto-iliac obstructive disease with kissing stents is a convenient method of restoring circulation in the suprainguinal arteries, with low mortality, morbidity and with good patency rates especially with TASC A, B, and selected TASC C cases. Endovascular treatment with the kissing stent technique has a super added value in improving the quality of life in patients with multi-level arterial occlusions. Patency of the aorto-iliac segment may improve the ABI of the patients with distal disease, thus reducing the need for distal bypasses. Extensive aorto-iliac involvement should be scheduled for open by-pass procedures according to the general status of the patient.

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